

REMARKS

Claims 34-36 and 46-48 are pending in this application. Claim 34 is amended for clarity and to correct informalities. The amendment is supported by the specification (see for example, see page 3 at [13] and page 9 at [31]). Claim 35 is amended to make the claim dependent of claim 34. Therefore, no new matter is introduced. The Office Action is discussed below:

Obviousness Rejection:

On pages 2-4 of the office action, the examiner has maintained the obviousness rejection of claims 34-36 and 46-48 allegedly as being unpatentable over Price *et al.* (WO 98/15614) in view of Kistner *et al.* (US 5,753,489). The examiner believes, although the term "soy hydrolysate" is not described on pages 19-20 of Price, page 19 lines 3-10 of Price discloses that plant peptides may be used in culture formulation by "digesting plant extracts with enzymes such as trypsin or chymotrypsin, by methods that are routine in the art or may be obtained commercially. According to the examiner Price discloses that:

additional nutrients added to medium may comprise extracts of yeast cells (refers to Price *et al.*, page 20, lines 8-20);

at least one peptide, extract, enzymatic digest or hydrolysate of plant protein, and/or at least one plant-derived lipid and/or fatty acid, is added to a basal medium to formulate the complete culture media of the present invention" (refers to Price *et al.*, page 18, lines 16-19); and

plants suitable as sources of proteins, peptides, lipids and/or fatty acids in formulating the culture media of the present invention include, but are not limited to, rice...soy...potato...and corn (refers to Price *et al.*, page 18, lines 20-23).

The examiner considers that Price *et al.* preferred rice, excluded wheat, but disclosed soy hydrolysates as a source of peptides, proteins, lipids and/or fatty acids, in medium in addition to yeast hydrolysate.

Regarding kidney cells, the examiner refers that Price *et al.* discloses BHK cells, which are kidney cells (refers to page 7, lines 21-29).

Applicants respectfully disagree with the examiner and submit that even if Price *et al.* discloses the term "soy hydrolysate", does not make the claimed invention obvious when combined with the disclosure of Kistner disclosure. Applicants refer to the examiner's previous Office Action of June 2, 2006 (see page 3), where the examiner miscalculated the Price *et al.* disclosure and believed that Price *et al.*, on pages 19-20, discloses a "medium comprising soy hydrolysate at a concentration of about .1% and yeast hydrolysate at a concentration of 0.1% to about .8%...." In fact, Price *et al.* discloses plant peptides in general and does not provide any concentration range for "soy hydrolysate" to inform the skilled artisan. Moreover, the generalized concentration range disclosed is "10-1000 mg/liter" for plant peptides (see Price *et al.* page 19, line 9) and "10-8000 mg/liter" for yeast extract (see Price *et al.* page 20, line 16), which is correctly calculated to be 1% to 100% for plant peptides (including Soy) and 1% to 800% for yeast extract. Applicants mention that one skilled in the art, by reading the Price *et al.* disclosure would not be able to arrive at the claimed invention in combination with the Kistner disclosure. Therefore, a combination of these references does not render the claimed invention obvious.

In order to expedite the prosecution and for clarity, without acquiescing in the rejection, applicants amend claim 34, without prejudice or disclaimer, to recite "purified soy hydrolysate at a concentration of about 0.05% (w/v) to less than about 1% (w/v)." The amendment is fully supported by the specification (see for example, see page 3 at [13] and page 9 at [31]). Applicants also amend claim 36 to make the claim dependent of claim 34.

The examiner also asserted, since the Price reference and the Kistner reference are both concerned with the culture of cells for virus production, it would have been obvious that one of ordinary skill in the art would have been motivated to do combine the two. Again, applicants disagree with the examiner and reiterate that Price suggests using "rice peptide" instead of "soy and/or yeast extracts." More specifically, applicants

quote from Price *et al.* - “[t]hese results demonstrate that, of the plant peptides tested as supplements for the culture media, the hydrolysate of rice performed most optimally.the results obtained with rice peptide supplementation were significantly higher than those obtained with either soy or yeast extracts.....Thus, rice hydrolysate is favored as a supplement in animal protein-free formulations of culture media suitable for the cultivation of animal cells.” (See Price *et al.* page 31, lines 9-16). Clearly, there is no motivation or any suggestion in Price *et al.* to use soy hydrolysate or yeast hydrolysate. In fact, Price *et al.* teaches away from the use of a culture medium comprising soy hydrolysate and/or yeast hydrolysate. Again, Price *et al.* point towards rice hydrolysates. See *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) (stating, “in general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.”).

Moreover, applicants indicate that with regard to both Price and Kistner, neither reference discloses an important feature of the currently claimed invention, notably that the “90% of the purified hydrolysates have a molecular weight of less than or equal to 1000 Dalton”. Neither reference describes the purification of soy or yeast hydrolysates to produce defined molecular weight fractions of the hydrolysates for use in animal protein free media. In order to further distinguish the claimed invention from the cited references, applicants amend claim 34, without prejudice or disclaimer, to recite that “at least 90% of the hydrolysate having a molecular weight of less than or equal to 1000 Daltons.” The amendment is fully supported by the specification (see for example, page 9 at [31]).

Applicants also indicate that, although Price *et al.* does mention, enzymatic digests of yeast, for example, on top of page 10 and on bottom of page 22, their use is not disclosed in the basic medium formulation. Rather, a general and unfocused statement is made that “animal derived products” may be substituted by “plant peptides, plant lipids, plant fatty acids, and/or enzymatic digests or extracts of yeast (or combinations thereof)”. For the formulations of media actually used and described in

the Price *et al.* disclosure, only "yeast extract" is used. In addition, the specific combination of concentration ranges in the claimed invention is not disclosed in the cited references.

Therefore, one of ordinary skilled in the art would not have been directed, at the time the instant application was filed, to combine the formulation as suggested by Price and the formulation of Kistner to arrive at the claimed invention.

Applicants also submit that the combination of Price and Kistner is nowhere supported by the references or in the common knowledge of the art.

In addition, Applicants indicate that Kistner *et al.* (US 5,753,489) do not rectify the deficiencies (see above) of Price *et al.* (WO 98/15614). Thus, a combination of Price and Kistner does not make the claimed inventions obvious.

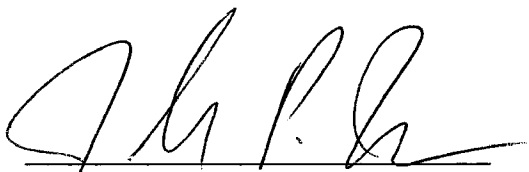
Therefore, withdrawal of the obviousness rejection is solicited.

REQUEST

Applicants submit that claims 34-36 and 46-48 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,

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Date



John P. Isacson
Reg. No. 33,715

PROSKAUER ROSE LLP
1001 Pennsylvania Avenue, N.W.
Suite 400 South
Washington, D.C. 20004
Phone: 202-416-6800
Fax: 202-416-6899
Customer No. 61263